

The effect of undetectable equals untransmittable (U=U) messaging on HIV testing uptake among South African men: a randomized trial.
[Short title: U=U]

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NCT04364165

Study Sponsors
Bill and Melinda Gates Foundation

CLIENT SITE

CODE: _____

E.G. ABCD1234 or STICKER

University of Cape Town - Department of Medicine

Informed Consent Form

Research Study: Messaging to improve HIV testing

Invitation and Purpose: We are researchers from the Department of Medicine at the University of Cape Town. You are invited to take part in a research study where you will be asked questions about messaging about HIV testing for men. The study started when the recruiter invited you to attend for an HIV test. We would like to understand if messaging about HIV treatment and its impact on preventing HIV transmission can improve HIV testing in men. You may have received a standard message about HIV testing or a new message about HIV treatment and prevention of HIV transmission, depending on the day you accessed our services. Your participation will help us understand if men who receive enhanced messaging improves HIV testing rates in men.

Procedures: If you decide to take part in this study, we will ask you survey questions about your experience of the invitation message which will take 15 minutes. As part of the usual clinic service, you will receive HIV testing and counselling. If you test HIV-positive, we will refer you for HIV treatment at the nearest clinic. If you agree, we will follow up medical records to see if you access treatment at the facility.

Risks, Discomforts & Inconveniences: There are no risks or discomforts over the standard HIV testing procedure. The fingerprick may be painful. Additionally, it may be distressing to receive an HIV positive result. All information you give is confidential. We will not share your results with anyone.

Benefits: This study will not benefit you directly. However, the knowledge we gain from it will be used to help develop improved messaging for men's sexual health services.

Alternatives (Other Options): You do not have to participate in this study—it is up to you.

Privacy and Confidentiality: We will take strict precautions to safeguard your personal information throughout the study. Your information will be kept without your name or personal identifiers. Your information will be identified with a code on a password-protected computer. Study data will be kept on a password-protected, secure server in the Department of Medicine at the Desmond Tutu HIV Foundation. Only the researchers will be able to access your personal information.

Questions: If you have questions, concerns, or complaints about the study, please contact Dr Dvora Joseph Davey on 021 650 1895. If you have any questions about the rights you have while taking part in this study, call Prof. M Blockman, Chairperson for the University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee, Old Main Building, Groote Schuur Hospital, Anzio Road, Observatory, Cape Town, 7925, South Africa, tel 021 406 6338; fax 021 406 6411) which is an independent committee established to help protect the rights of research participants. This is a group of scientific and non-scientific individuals who review research studies with the safety and welfare of research participants in mind and gave their positive opinion to this research study.

Signatures: {Participant's name} _____ has been informed of the nature and purpose of the procedures described above including any risks involved in its performance. He or she has been given time to ask any questions and these questions have been answered to the best of the investigator's ability. A signed copy of this consent form will be made available to the participant.

I have been informed about this research study and understand its purpose, possible benefits, risks, discomforts and that the researchers we will follow up my medical records. I agree to take part in this research as a subject. I know that I am free to withdraw this consent and quit this project at any time, and that doing so will not cause me any penalty or loss of benefits that I would otherwise be entitled to enjoy.

I consent (please check)

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Participants name: _____ Participants signature: _____ Date: _____

Investigators name: _____ Investigators signature: _____ Date: _____